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Chapter 1 – Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K03 3127

1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4469

Contact Person: Sarah Parsons

Date 510(k) prepared: September 29, 2003

2. Device Name

Trade or Proprietary Name: *Vitros* Immunodiagnostic Products Anti-HBc Controls
Common Name: anti-HBc controls
Classification Name: 21CFR 862.1660 Quality Control Material (Assayed and Unassayed).

3. Predicate Device

The *Vitros* Immunodiagnostic Products Anti-HBc Controls are substantially equivalent to Blackhawk BioSystems, Inc. VIROTROL® I (BK930016).

4. Device Description

Vitros Anti-HBc Controls contain two levels of controls in separate vials.

Control 1
Normal human plasma obtained from donors who were tested individually and found to be negative for hepatitis B surface antigen (HBsAg), and for antibodies to human immunodeficiency virus (anti-HIV 1+2) and hepatitis C virus (anti-HCV) using FDA approved methods (enzyme immunoassays).

Control 2
Anti-HBc positive plasma diluted in normal human plasma. Both plasmas were obtained from donors who were tested individually and found to be negative HBsAg, and for antibodies to

HIV 1+2 and HCV using FDA approved methods (enzyme immunoassays). The anti-HBc positive plasma has also been tested and shown to be positive for anti-HBc antibody.

Both controls contain antimicrobial agent.

The controls are assigned values from a minimum of 10 assays. The standard deviation is that which would be anticipated for single determinations of each control in a number of different laboratories using different reagent batches.

5. Device Intended Use

The *Vitros* Anti-HBc Controls are intended for use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of total antibody (IgG and IgM) to hepatitis B core antigen (total anti-HBc) in human serum and plasma (EDTA and citrate). The performance of the *Vitros* Immunodiagnostic Products Anti-HBc Controls has not been established with any other anti-HBc assays.

6. Comparison to Predicate Device

The *Vitros* Immunodiagnostic Products Anti-HBc Controls are substantially equivalent to Blackhawk BioSystems, Inc. VIROTROL® I (BK930016).

Table 1 lists the similarities and differences of the device characteristics between the *Vitros* Anti-HBc Controls and the predicate device.

Table 1 Characteristics of the Controls

Characteristics	New Device	Predicate Device
Intended use	For use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of total antibody (IgG and IgM) to hepatitis B core antigen (total anti-HBc) in human serum and plasma (EDTA and citrate). The performance of the *Vitros* Immunodiagnostic Products Anti-HBc Controls has not been established with any other anti-HBc assays.	VIROTROL I is intended for use with in vitro assay procedures for determination of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1), antibodies to Human T-Lymphotropic Virus Type I (HTLV-I), antibodies to Hepatitis C Virus (HCV), Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis B Core Antigen (HBc) and antibodies to cytomegalovirus (CMV). VIROTROL reagents are intended to provide a means of estimating precision and have the potential for detecting systematic deviations from specific laboratory testing procedures.
Matrix of controls	Human serum with added antimicrobial agents	Human serum or plasma with added stabilizers and preservative.
Control levels	Positive and negative	Positive
Expected values	Each control has a quoted mean value derived from a minimum of 10 assays and a standard deviation anticipated for single determinations of each control in a number of different laboratories using different reagent lots. Values are lot specific.	VIROTROL 1® controls do not have assigned values, but are formulated to produce positive reactivity in the listed manufacturer's assays. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent lot numbers, and different laboratories. Each laboratory should establish its own range of acceptable values for each analyte.

7. Conclusions

The information presented in the pre-market notification demonstrates that the *Vitros* Anti-HBc Controls are substantially equivalent to the predicate device Blackhawk BioSystems, Inc. VIROTROL 1® Multi-Marker Positive Control which was cleared by FDA (BK930016).

The information presented in the premarket notification provide a reasonable assurance that the *Vitros* Anti-HBc Controls are safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 31 2003

Ms. Sarah Parsons
Associate, Regulatory Affairs
Ortho Clinical Diagnostics
100 Indigo Creek Park
Rochester, NY 14626-5101

Re: k033127
Trade/Device Name: *Vitros* Immunodiagnostic Products Anti-HBc Controls
Regulation Number: 21 CFR 866.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: September 29, 2003
Received: September 30, 2003

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K033127

Device Name:

Vitros Immunodiagnostic Products Anti-HBc Controls

Indications for Use:

For use in monitoring the performance of the *Vitros* ECi Immunodiagnostic System when used for the *in vitro* qualitative detection of total antibody (IgG and IgM) to hepatitis B core antigen (total anti-HBc) in human serum and plasma (EDTA and citrate). The performance of the *Vitros* Immunodiagnostic Products Anti-HBc Controls has not been established with any other anti-HBc assays.

(PLEASE DO NOT WRITE BELOW THIS LINE ~~CONTINUE ON~~ ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Prescription Use ✓ (Per 21 CFR 801.109) Over-The-Counter Use _____

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional Format 1-2-96)

510(k) K033127